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2. are provided by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients; and

3. except in the case of nurse-midwife services, as specified in 42 CFR §440.165, are furnished by or under the direction of a physician or dentist.

10. Dental services.

A. Dental services are limited to recipients under 21 years of age in fulfillment of the treatment requirements under the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program and defined as routine diagnostic, preventive, or restorative procedures necessary for oral health provided by or under the direct supervision of a dentist in accordance with the State Dental Practice Act.

B. Initial, periodic, and emergency examinations; required radiography necessary to develop a treatment plan; patient education; dental prophylaxis; fluoride treatments; routine amalgam and composite restorations; stainless steel crowns, prefabricated steel post, temporary (polycarbonate crowns) and stainless steel bands; crown recementation; pulpotomies; emergency endodontics for temporary relief of pain; pulp capping; sedative fillings; therapeutic apical closure; topical palliative treatment for dental pain; removal of foreign body; simple extractions; root recovery; incision and drainage of abscess; surgical exposure of the tooth to aid eruption; sequestrectomy for osteomyelitis; and oral antral fistula closure are dental services covered without preauthorization by the State Agency.

C. All covered dental services not referenced above require preauthorization by the State Agency. The following services are also covered through preauthorization: medically necessary full banded orthodontics, tooth guidance appliances, complete and partial dentures, surgical preparation (alveoloplasty) for prosthetics, single permanent crowns, and bridges. The following service is not covered: routine bases under restorations and inhalation analgesia.

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D. The State Agency may place appropriate limits on a service based on medical necessity and/or for utilization control. Examples of service limitations are: examinations, prophylaxis, fluoride treatment (once/six months); space maintenance appliances; bitewing x-ray -- two films (once/twelve months); routine amalgam and composite restorations (once/three years); dentures (once per 5 years); extractions, orthodontics, tooth guidance appliances, permanent crowns and bridges, endodontics, patient education and sealants (once).

E. Limited oral surgery procedures, as defined and covered under Title XVIII (Medicare), are covered for all recipients, and also require preauthorization by the State Agency.

12 VAC 30-50-200. Physical therapy and related services.

11. Physical therapy and related services. Physical therapy and related services shall be defined as physical therapy, occupational therapy, and speech-language pathology services. These services shall be prescribed by a physician and be part of a written physician's order/plan of care. Any one of these services may be offered as the sole service and shall not be contingent upon the provision of another service. All practitioners and providers of services shall be required to meet State and Federal licensing and/or certification requirements. Services shall be provided according to guidelines found in the Virginia Medicaid Rehabilitation Manual.

11a. Physical Therapy.

A. Services for individuals requiring physical therapy are provided only as an element of hospital inpatient or outpatient service, nursing facility service, home health service, or when otherwise included as an authorized service by a cost provider who provides rehabilitation services.

B. Effective with dates of service on and after October 24, 1995, DMAS will provide for the direct reimbursement to enrolled rehabilitation providers for physical therapy services, when such services are rendered to patients residing in nursing facilities (NFs). Such reimbursement shall not be provided for any sums that the rehabilitation provider collects, or is entitled to collect, from the NF or any other available source, and provided further, that this amendment shall in no way diminish any obligation of the NF to DMAS to provide its residents such services, as set forth in any applicable provider agreement.

11b. Occupational therapy.

A. Services for individuals requiring occupational therapy are provided only as an element of hospital inpatient or outpatient service, nursing facility service, home health service, or when otherwise included as an authorized service by a cost provider who provides rehabilitation services.

B. Effective with dates of service on and after October 24, 1995, DMAS will provide for the direct reimbursement to enrolled rehabilitation providers for occupational therapy services, when such services are rendered to patients residing in nursing facilities (NFs). Such reimbursement shall not be provided for any sums that the rehabilitation provider collects, or is entitled to collect, from the NF or any other available source, and provided further, that this amendment shall in no way diminish any

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obligation of the NF to DMAS to provide its residents such services, as set forth in any applicable provider agreement.

11c. Services for individuals with speech, hearing, and language disorders (provided by or under the supervision of a speech pathologist or audiologist.)

A. These services are provided by or under the supervision of a speech pathologist or an audiologist only as an element of hospital inpatient or outpatient service, nursing facility service, home health service, or when otherwise included as an authorized service by a cost provider who provides rehabilitation services.

B. Effective with dates of service on and after October 24, 1995, DMAS will provide for the direct reimbursement to enrolled rehabilitation providers for speech/language therapy services, when such services are rendered to patients residing in nursing facilities (NFs). Such reimbursement shall not be provided for any sums that the rehabilitation provider collects, or is entitled to collect, from the NF or any other available source, and provided further, that this amendment shall in no way diminish any obligation of the NF to DMAS to provide its residents such services, as set forth in any applicable provider agreement.

11d. Authorization for outpatient rehabilitation services.

A. Physical therapy, occupational therapy, and speech-language pathology services provided in outpatient settings of acute and rehabilitation hospitals, rehabilitation agencies, school divisions, or home health agencies shall include authorization for up to 24 visits by each ordered rehabilitative service annually. The provider shall maintain documentation to justify the need for services.

B. The provider shall request from DMAS authorization for treatments deemed necessary by a physician beyond the number authorized. Documentation for medical justification must include physician orders or a plan of care signed and dated by a physician. Authorization for extended services shall be based on individual need. Payment shall not be made for additional service unless the extended provision of services has been authorized by DMAS.

C. Covered outpatient rehabilitative services for acute conditions shall include physical therapy, occupational therapy, and speech-language pathology services. "Acute conditions" shall be defined as conditions which are expected to be of brief duration (less than twelve months) and in which progress toward established goals is likely to occur frequently.

D. Covered outpatient rehabilitation services for long-term, non-acute conditions shall include physical therapy, occupational therapy, and speech-language pathology services. "Non-acute conditions" shall be defined as those conditions which are of long duration (greater than twelve months) and in which progress toward established goals is likely to occur slowly.

E. Payment shall not be made for reimbursement requests submitted more than twelve months after the termination of services.

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11e. Service Limitations. The following general conditions shall apply to reimbursable physical therapy, occupational therapy, and speech-language pathology:

A. Patient must be under the care of a physician who is legally authorized to practice and who is acting within the scope of his license.

B. The physician orders for therapy services shall include the specific procedures and modalities to be used, identify the specific discipline to carry our the physician's order/plan of care, and indicate the frequency and duration for services. Physician orders/plan of care must be personally signed and dated prior to the initiation of rehabilitative services. The certifying physician may use a signature stamp, in lieu of writing his full name, but the stamp must, at minimum, be initialed and dated at the time of the initialing within 21 days of the order.

C. Services shall be furnished under a written plan of treatment and must be established, signed, and dated (as specified in this section) and periodically reviewed by a physician. The requested services or items must be necessary to carry out the plan of treatment and must be related to the patient's condition.

D. A physician recertification shall be required periodically, must be signed and dated (as specified in this section) by the physician who reviews the plan of treatment. The physician recertification statement must indicate the continuing need for services and should estimate how long rehabilitative services will be needed. Certification and recertification must be signed and dated (as specified in this section) prior to the beginning of rehabilitation services.

E. Utilization review shall be performed to determine if services are appropriately provided and to ensure that the services provided to Medicaid recipients are medically necessary and appropriate. Services not specifically documented in the patient's medical record as having been rendered shall be deemed not to have been rendered and no coverage shall be provided.

F. Physical therapy, occupational therapy and speech-language services are to be considered for termination regardless of the preauthorized visits or services when any of the following conditions are met:

1. No further potential for improvement is demonstrated. The patient has reached his maximum progress and a safe and effective maintenance program has been developed.

2. There is limited motivation on the part of the individual or caregiver.

3. The individual has an unstable condition that affects his or her ability to participate in a rehabilitative plan.

4. Progress toward an established goal or goals cannot be achieved within a reasonable period of time.

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5. The established goal serves no purpose to increase meaningful functional or cognitive capabilities.

6. The service can be provided by someone other than a skilled rehabilitation professional.

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12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

A. Prescribed drugs.

1. Drugs for which Federal Financial Participation is not available, pursuant to the requirements of §1927 of the Social Security Act (OBRA '90 §4401), shall not be covered.

2. Nonlegend drugs shall be covered by Medicaid in the following situations:
   a. Insulin, syringes, and needles for diabetic patients;
   b. Diabetic test strips for Medicaid recipients under 21 years of age;
   c. Family planning supplies;
   d. Designated categories of nonlegend drugs for Medicaid recipients in nursing homes;
   e. Designated drugs prescribed by a licensed prescriber to be used as less expensive therapeutic alternatives to covered legend drugs.

3. Legend drugs are covered with the exception of the drugs or classes of drugs identified in 12VAC30-50-520 (Supplement 5 to Attachment 3.1 A&B). FDA-approved drug therapies and agents for weight loss, when preauthorized, will be covered for recipients who meet the strict disability standards for obesity established by the Social Security Administration in effect on April 7, 1999, and whose condition is certified as life threatening, consistent with Department of Medical Assistance Services' medical necessity requirements, by the treating physician.

4. Notwithstanding the provisions of §32.1-87 of the Code of Virginia, and in compliance with the provision of §4401 of the Omnibus Reconciliation Act of 1990, §1927(e) of the Social Security Act as amended by OBRA 90, and pursuant to the authority provided for under §32.1-325 A of the Code of Virginia, prescriptions for Medicaid recipients for multiple source drugs subject to 42 CFR 447.332 shall be filled with generic drug products unless the physician or other practitioners so licensed and certified to prescribe drugs certifies in his own handwriting "brand necessary" for the prescription to be dispensed as written.

5. New drugs shall be covered in accordance with the Social Security Act §1927(d) (OBRA 90 §4401).

6. The number of refills shall be limited pursuant to §54.1-3411 of the Drug Control Act.

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G. Drug Prior Authorization.

1. Definitions. The following words and terms, when used in these regulations, shall have the following meaning, unless the context clearly indicates otherwise:
"Board" means the Board of Medical Assistance Services.
"Committee" means the Medicaid Prior Authorization Advisory Committee.
"Department" means the Department of Medical Assistance Services.
"Director" means the Director of Medical Assistance Services.
"Drug" shall have the same meaning, unless the context otherwise dictates or the Board otherwise provides by regulation, as provided in the Drug Control Act (§54.1-3400 et seq.).

2. Medicaid Prior Authorization Advisory Committee: membership. The Medicaid Prior Authorization Advisory Committee shall consist of eleven members to be appointed by the Board. Five members shall be physicians, at least three of whom shall care for a significant number of Medicaid patients; four shall be pharmacists, two of whom shall be community pharmacists; one member shall be a consumer of mental health services; and one member shall be a Medicaid recipient.

   a. A quorum for action of the Committee shall consist of six members.

   b. The members shall serve at the pleasure of the Board: vacancies shall be filled in the same manner as the original appointment.

   c. The Board shall consider nominations made by The Medical Society of Virginia, the Old Dominion Medical Society, the Psychiatric Society of Virginia, the Virginia Pharmaceutical Association, the Virginia Alliance for the Mentally Ill and the Virginia Mental Health Consumers Association when making appointments to the Committee.

   d. The Committee shall elect its own officers, establish its own procedural rules, and meet as needed or as called by the Board, the Director, or any two members of the Committee. The Department shall provide appropriate staffing to the Committee.

3. Duties of the Committee.

   a. The Committee shall make recommendations to the Board regarding drugs or categories of drugs to be subject to prior authorization, prior authorization requirements for prescription drug coverage and any subsequent amendments to or revisions of the prior authorization requirements. The Board may accept or reject the recommendations in whole or in part, and may amend or add to the recommendations, except that the Board may not add to

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the recommendation of drugs and categories of drugs to be subject to prior authorization.

b. In formulating its recommendations to the Board, the Committee shall not be deemed to be formulating regulations for the purposes of the Administrative Process Act (§ 9-6.14:1 et seq.). The Committee, shall, however, conduct public hearings prior to making recommendations to the Board. The Committee shall give thirty days' written notice by mail of the time and place of its hearings and meetings to any manufacturer whose product is being reviewed by the Committee and to those manufacturers who request the Committee in writing that they be informed of such hearings and meetings. These persons shall be afforded a reasonable opportunity to be heard and present information. The Committee shall give thirty days' notice of such public hearings to the public by publishing its intention to conduct hearings and meetings in the Calendar of Events of the Virginia Register of Regulations and a newspaper of general circulation located in Richmond.

c. In acting on the recommendations of the Committee, the Board shall conduct further proceedings under the Administrative Process Act.

4. Prior Authorization of prescription drug products: coverage.

a. The Committee shall review prescription drug products to recommend prior authorization under the state plan. This review may be initiated by the Director, the Committee itself, or by written request of the Board. The Committee shall complete its recommendations to the Board within no more than six months from receipt of any such request.

b. Coverage for any drug requiring prior authorization shall not be approved unless a prescribing physician obtains prior approval of the use in accordance with regulations promulgated by the Board and procedures established by the Department.

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c. In formulating its recommendations to the Board, the Committee shall consider the potential impact on patient care and the potential fiscal impact of prior authorization on pharmacy, physician, hospitalization and outpatient costs. Any proposed regulation making a drug or category of drugs subject to prior authorization shall be accompanied by a statement of the estimated impact of this action on pharmacy, physician, hospitalization and outpatient costs.

d. The Committee shall not review any drug for which it has recommended or the Board has required prior authorization within the previous twelve months, unless new or previously unavailable relevant and objective information is presented.

e. Confidential proprietary information identified as such by a manufacturer or supplier in writing in advance and furnished to the Committee or the Board according to this section shall not be subject to the disclosure requirements of the Virginia Freedom of Information Act (§ 2.1-340 et seq.). The Board shall establish by regulation the means by which such confidential proprietary information shall be protected.

5. Immunity. The members of the Committee and of the Board and the staff of the Department shall be immune, individually and jointly, from civil liability for any act, decision, or omission done or made in performance of their duties pursuant to this article while serving as a member of such Board, Committee, or staff provided that such act, decision, or omission is not done or made in bad faith or with malicious intent.

6. Annual report to Joint Commission. The Committee shall report annually to the Joint Commission on Health Care regarding its recommendations for prior authorization of drug products.

12b. Dentures.

A. Provided only as a result of EPSDT and subject to medical necessity and preauthorization requirements specified under Dental Services.

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12c. Prosthetic devices.

A. Prosthetics services shall mean the replacement of missing arms and legs. Nothing in this regulation shall be construed to refer to orthotic services or devices.

B. Prosthetic devices (artificial arms and legs, and their necessary supportive attachments) are provided when prescribed by a physician or other licensed practitioner of the healing arts within the scope of their professional licenses as defined by state law. This service, when provided by an authorized vendor, must be medically necessary, and preauthorized for the minimum applicable component necessary for the activities of daily living.

12d. Eyeglasses.

A. Eyeglasses shall be reimbursed for all recipients younger than 21 years of age according to medical necessity when provided by practitioners as licensed under the Code.

12 VAC 30-50-220.

13. Other diagnostic, screening, preventive, and rehabilitative services, i.e., other than those provided elsewhere in this plan.

13a. Diagnostic services.

A. Provided, but only when necessary to confirm a diagnosis.

13b. Screening services.

A. Screening mammograms for the female recipient population aged 35 and over shall be covered, consistent with the guidelines published by the American Cancer Society.

B. Screening PSA (meaning prostate specific antigen) and the related DRE (meaning digital rectal examination) for males shall be covered, consistent with the guidelines published by the American Cancer Society.

C. Screening Pap smears shall be covered annually for females consistent with the guidelines published by the American Cancer Society.

13c. Preventive services.

A. Maternity length of stay and early discharge.

1. If the mother and newborn, or the newborn alone, is discharged earlier than 48 hours after the day of delivery, DMAS will cover one early discharge follow-up visit as recommended by the physicians in accordance with and as